(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 564 492 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 13.10.1999 Bulletin 1999/41

(21) Application number: 92901032.0

(22) Date of filing: 21.11.1991

(51) Int. Cl.[6]: A61B 5/021, A61B 5/029

(86) International application number: PCT/US91/08710

(87) International publication number: WO 92/11805 (23.07.1992 Gazette 1992/19)

(54) VASCULAR IMPEDANCE MEASUREMENT INSTRUMENT

VORRICHTUNG ZUR MESSUNG DER IMPEDANZ VON BLUTGEFÄSSEN

INSTRUMENT DE MESURE D'IMPEDANCE VASCULAIRE

(84) Designated Contracting States:
DE FR GB

(30) Priority: 28.12.1990 US 635278

(43) Date of publication of application:
13.10.1993 Bulletin 1993/41

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Printed by Xerox (UK) Business Services
2.16.7/3.6

Description

Technical Field of the Invention

[0001] The present invention pertains generally to the field of cardiovascular medicine, and more particularly, to an instrument for characterizing the status of the cardiovascular system using an electrical analog model thereof.

Background of the Invention

[0002] The article "Eine neue nichtinvasive Pulskontur-Schlagvolumenbestimmungsmethode aufgrund eines Optimierungsmodells der Herzarbeit" from W. Estelberger on pages 212 to 217 of Biomedizinische Technik, vol. 22, No. 9, 1977, discloses a method for the calculation of the stroke volume of the heart by means of non-invasively recorded pressure pulse registrations. Such procedure is based on Broemer's idea formulated in a model of Yamashiro et al. to the effect that the ejection work of the left ventricle is subject to an optimization principle. Such model of optimal control of the ejection process permits the determination of cardiovascular parameters on the basis of a knowledge of the central pressure pulse through parameter adaption of the computed to the observed pressure pulse curve.

[0003] The modified Windkessel electrical analog model of the arterial system is gaining increasing attention from the medical community as a clinically useful tool for characterizing the human vasculature for the purpose of diagnosing, treating and monitoring cardiovascular disease. A number of studies of the cardiovascular system using the modified Windkessel model have been conducted, and correlations between the model parameters and normal and disease states have been identified. For instance, WO-A-90/03145 discloses a method for utilizing the parameter C_2 of the modified Windkessel model to diagnose, treat and monitor the vascular disease condition underlying hypertension.

[0004] The modified Windkessel model of the arterial system is shown in Fig. 1. In the model:

C_1 = proximal arterial compliance ($m\ell$/mm Hg);
C_2 = distal arterial compliance ($m\ell$/mm Hg);
L = inertence (mm Hg/$m\ell/s^2$);
P_1 = proximal arterial (aortic) pressure (mm Hg);
P_2 = distal arterial (brachial) pressure (mm Hg); and
R = peripheral resistance (dynes sec cm^{-5}).

[0005] While the usefulness of the Windkessel model parameters for the diagnosis, treatment and monitoring of cardiovascular disease has become more apparent, they remain relatively difficult to use on a routine basis for two reasons. The first is the need to obtain a cardiac output measurement in order to determine the parameter. Conventional procedures for determining cardiac output, such as thermodilution and dye dilution, are surgically invasive, requiring catheterization of the patient. Physicians, in general, are reluctant to employ such procedures because of their cost, the discomfort and inconvenience to the patient, the risk of infection and other severe complications and their relative level of complexity as compared to alternative noninvasive procedures. The second reason involves the difficulty with obtaining patient data for the modified Windkessel model from blood pressure waveforms, which also conventionally requires the insertion of an arterial catheter and the use of a transducer and other electronic equipment.

Summary of the Invention

[0006] According to the present invention, there is provided a vascular impedance properties measurement instrument, comprising means for measuring arterial pressure and producing a corresponding series of digitized data samples representing the waveform of the arterial blood pressure of a patient, means for determining the mean arterial pressure of the patient from said data sample series, means for determining a cardiac output value for the patient from said data sample series, and means for displaying or reporting one or more parameters, characterized by means for determining the heart rate and the systolic ejection time of the patient from said data sample series, and means for determining the stroke volume of the patient from said systolic ejection time, the patient's body surface area and the patient's age, wherein said means for determining a cardiac output value for the patients determines the cardiac output value from said heart date and said stroke volume, and further characterized by means for determining for the patient one or more of the parameters of a vascular impedance model from said data sample series and from said cardiac output value.

[0007] Further advantageous embodiments are defined in the sub-claims.

[0008] The present invention provides an instrument which can noninvasively measure Windkessel parameters, or other impedance parameters which depend on cardiac output measurement, using a noninvasively obtained arterial blood pressure waveform of the patient. Accordingly, it is contemplated that the present invention will significantly facil-

itate widespread clinical use of the modified Windkessel model parameters, or other impedance model parameters, in the diagnosis, treatment and monitoring of cardiovascular disease. In particular, the invention allows for a quick, easy-to-use and noninvasive determination of the modified Windkessel parameters so that these parameters can be ascertained and used during routine physical examinations, and patient screening, treatment and monitoring. Given that the only existing practical and quick screening device for determining the status of the cardiovascular state is a blood pressure cuff (i.e., a sphygmomanometer) measurement, it is contemplated that the invention could provide a substantial and new diagnostic capability for physicians to use on a routine basis.

[0009] The present invention recognizes that usable and useful Windkessel parameter measurements can be obtained even if the cardiac output value used to obtain the measurements are not particularly accurate. Accordingly, the present invention provides that cardiac output measurements be obtained noninvasively, using the same arterial blood pressure waveform used to obtain the Windkessel model parameter measurements.

Brief Description of the Drawing

[0010]

Fig. 1 is a circuit diagram of a modified Windkessel model of the vascular circulation;
Fig. 2 is a schematic block diagram of the modified Windkessel parameter vascular impedance measurement instrument according to the present invention;
Fig. 3 is a schematic flow chart of the software components of the present invention;
Fig. 4 is an illustrative example of a typical arterial blood pressure pulse contour or waveform in a healthy patient with the systolic ejection time marked as segment A; and
Fig. 5 is an illustrative example of typical arterial blood pressure pulse contour or waveform in a healthy patient with the diastolic decay time of the waveform marked as segment B.

Detailed Description of the Invention

[0011] The modified Windkessel parameter vascular impedance measurement instrument 10 according to the present invention is shown in simplified schematic block diagram form in Fig. 2. The instrument 10 includes a transducer unit 34, a computer system 11, and optionally a printer 42. System 11 includes an analog to digital convertor (A/D) 12, preferably 12-bit, and a microprocessor unit 14, for instance a model 80386 by Intel, a keyboard input 16, a display 18, a ROM 20, a RAM 22 and a storage device 24. An input port 30 is provided to receive analog signal input from an arterial pressure transducer unit 34. Microprocessor 14 includes an output port 38 connected to optional printer 42.

[0012] Transducer unit 34 is preferably a noninvasive arterial blood pressure waveform measurement device, for example, a finger-cuff transducer unit using a counter pulsation technique wherein the waveform is detected by balancing the air pressure in a finger cuff with the blood pressure in the patient's finger. A commercially available finger-cuff transducer unit of this type is the Finapres® Continuous NIBP Monitor Model 2300, from Ohmeda Monitoring Systems division of the BOC Group, Inc., 355 Inverness Drive South, Engelwood, Colorado 80112-5810. The Finapres® device produces an analog output signal which is fed through port 30 to A/D converter 12. Another noninvasive transducer unit available for use with the present invention is the Model 506 Non-Invasive Patient Monitor from Criticare Systems, Inc., 20900 Swenson Drive, Suite 398, Waukesha, Wisconsin 53186. A third commercially available transducer unit is the Model CMB-7000 from Nellcor Incorporated, 25495 Whitesell Street, Hayward, California 94545. This unit noninvasively measures arterial blood pressure and provides waveform data based on the technique of arterial tonometry. It is also contemplated that the measured waveform may be transformed in digital form from the transducer unit 34 directly to the microprocessor 14, avoiding the need for A/D converter 12.

[0013] The arterial waveform may also be obtained invasively, if desired, although this is not believed to be preferred from a cost, medical risk and patient convenience perspective, using a Statham P23Db pressure transducer as unit 34. If obtained invasively, preferably, such a transducer would be connected to a patient's brachial artery via an 18-gauge, 2-inch Teflon catheter. This catheter-transducer system has an undamped natural frequency higher than 25 HZ and a damping coefficient less than 0.5, providing an acceptable frequency response. It shall be understood, however, that while the brachial artery is preferred, other peripheral arterial locations for obtaining the blood pressure waveforms can be substituted.

[0014] The software component 50 of the invention is illustrated in block diagram flow-chart form in Fig. 3. Software 50 is preferably stored in ROM 20 or storage device 24, and is referenced by microprocessor 14. Storage device 24 can be a hard disk, floppy disk or other digital storage system.

[0015] Software 50 runs on microprocessor 14 to control the acquisition of arterial blood pressure waveform data, and to perform other instrument functions, as described below. An initialization and mode select routine 52 is provided for initializing microprocessor 14, including prompting the user to enter patient information, including the patient's age,

height, weight, and/or body surface area. Routine 52 further provides that the waveform measurement process may be activated. If activated, A/D convertor 12 is activated (54) to digitize an analog blood pressure waveform signal generated by transducer 34. (Alternatively, as noted above, microprocessor 14 could obtain the pressure pulse measurements in digital form directly from transducer unit 34, if available, without the use of digitizer 54). Figs. 4 and 5 illustrate typical arterial blood pressure waveforms for healthy patients.

[0016] The present invention uses an A/D sampling rate of 200 samples/second, which is satisfactory to capture the highest frequency components of interest in the arterial blood pressure waveform. It shall be understood, however, that higher or lower sampling rates may be used, and that the invention is in no way limited to the 200 samples/second rate. Routine 56 provides that the waveform data is sampled for approximately 30 seconds, producing in the range of 25 to 60 digitized arterial pulses, depending on the heart rate. The stream of digitized pulses are stored in RAM 22 or device 24 in the form of a continuous series of periodic time dependent data byte samples, with each data byte corresponding to the instantaneous pressure of the artery.

[0017] Routine 60 determines body surface area by standard formula, or alternatively, looks it up in a nomogram table stored in memory, using the patient's height and weight data. Alternatively, body surface area (BSA) can be determined by the physician or other care giver and entered directly into the instrument at routine 52, as noted above. A formula for determining BSA known to work in connection with the present invention is:

$$\mathrm{BSA}\ (m^{-2}) = 0.0072 \times \mathrm{weight}^{0.425} \times \mathrm{height}^{0.725}$$

where weight is in kilograms and height is in centimeters.

[0018] A nomogram table known to work with the present invention is found in the Merck Manual, 12th edition, 1972 on page 1840 (reproduced from Wm. Brothby and R. B. Sandford, Boston Medical and Surgical Journal, Vol. 185, page 337, 1921).

[0019] Routine 70 performs three functions: (1) it selects consecutive heart beats; (2) determines the heart rate; and (3) determines the systolic ejection time of the heart.

[0020] First, routine 70 selects a group of consecutive representative beats (it has been found that six to ten beats are preferred, but the number used is in no way critical to the invention) preferably of comparatively low noise content. Representative beats are identified by establishing windows of permissible heart rate and mean arterial pressure values whereby abnormally fast or slow heartbeats, or high or low pressures can be rejected. The routine can thus pick the series of beats which is most representative.

[0021] Second, the heart rate (HR) is also determined by routine 70, by counting the number of beats per unit time. Where possible, it is preferable that the windows be tailored to the patient, thus allowing more precise selection of representative heart beats.

[0022] Thirdly, routine 70 determines systolic ejection time as follows. First, the arterial blood pressure waveforms are marked for analysis. When marked manually, a clinician can identify the onset of systole by the initial upstroke of arterial pressure. The end of systole, which is the onset of diastole, can be found manually by correlating to the second heart sound S_2, or by identifying the dicrotic notch on the arterial pressure wave. Ejection time is then determined by the time between the onset of systole and the beginning of diastole. For example, in Fig. 4, systolic ejection time is marked by segment A assuming a waveform obtained in the root of the aorta.

[0023] The present invention uses a software analysis algorithm at routine 70 to predict and select the segment A for each pressure waveform most probably corresponding to ejection time. Routine 70 searches the waveform data for the waveform upstroke marking systole, and then for the dicrotic notch (D), looked for after the peak of the systolic upstroke, and marks the onset of diastole just before the location of the dicrotic notch on the waveform. The ejection time (ET) is then determined from the location of the onset of systole and diastole. Transit time effects due to the distance between the proximal aorta and the arterial measurement site are taken into account in the ejection time measurement by moving back a predetermined interval (depending on where the arterial waveform is obtained in the arterial system) from the trough of the dicrotic notch to determine the end of systole for the purposes of the ejection time determination. The ejection time is thus the time between the upstroke (beginning of systole) and this point marking the end of systole. For waveforms obtained from the femoral or brachial artery, an interval of about 25 milliseconds has been found satisfactory to compensate for transit time effects. Shorter or longer intervals would be appropriate for waveforms obtained closer to or further from the heart, respectively.

[0024] Alternatively, instrument 10 can include means for digitizing an analog signal representing the heart sounds, software for identifying the first and second heart sounds S_1 and S_2, and for correlating them to the digitized arterial waveform to identify the onset of systole and diastole.

[0025] Routine 71 calculates stroke volume (SV) using the heart rate (HR), body surface area (BSA), ejection time (ET) and age for the subject, according to the following formula:

$$\mathrm{SV} = -6.6 + (0.25 \times \mathrm{ET}) + (40.4 \times \mathrm{BSA}) - (0.51 \times \mathrm{Age}) - (0.62 \times \mathrm{HR}),$$

where SV equals stroke volume in mℓ/beat, ET is ejection time in msec, BSA is body surface area in square meters, Age is expressed in years, and HR is heart rate in beats per minute.

[0026] Once SV is known, cardiac output can be determined by multiplying heart rate (HR) times stroke volume (SV).

[0027] The cardiac output values obtained by the above-described system are relatively accurate. In approximately 90% of known cases the measurements have been within plus or minus 25% of the measurement obtained using a so-called "Gold Standard" thermodilution or dye dilution technique. This accuracy compares quite favorably against the 15-20% reproducibility of these dilution techniques. It is currently contemplated that the formula for determining cardiac output set forth herein will be further refined and adjusted as additional data are collected and/or as adjustments to constants and factors are determined to produce more accurate determinations of cardiac output. The formula may be adjusted by performing a multiple linear regression to fit a new formula on "Gold Standard" data. Also, the particular formula set forth herein is not essential to the Windkessel parameter vascular impedance measurement instrument of the present invention. Other formulas and/or approaches to obtaining cardiac output measurements using the blood pressure waveform can be substituted for the particular formula set forth herein, provided that they give a reasonable degree of accuracy of measurement.

[0028] A routine 72 is provided to calculate the mean arterial pressure utilizing the blood pressure waveform data. The mean pressure value is used, as described herein, to determine the modified Windkessel parameters. With a cardiac output and mean arterial pressure value, the modified Windkessel parameters may be determined. To ascertain the modified Windkessel variables, the diastolic portion (i.e. that part of the pressure wave which corresponds to the period of diastole in the heart) of each selected beat must be identified and a routine 74 is provided for this purpose.

[0029] When marked manually, a clinician can identify the onset of diastole by correlating the second heart sound S_2 and the end of diastole by the upstroke of the following pulse. For example, in Fig. 5, diastole is marked by the segment B. However, for the sake of speed and simplicity, the present invention uses a software analysis algorithm to predict and select the segment in each pressure waveform most probably corresponding to diastole. Precise detection of onset is generally not critical because the slope of the pulse wave is generally uniform in the range of diastole onset. It is, however, important that the onset of the diastolic waveform to be used occur after the peak of systole and preferably within twenty milliseconds after the dicrotic notch (D). Thus, routine 74 searches the digital waveform representation for the dicrotic notch and marks the onset of diastole immediately thereafter on the waveform. The end of diastole in the waveform is easily located by finding the upstroke of the next pulse. With the relevant waveform segments so marked, the data for each pressure waveform can be analyzed to reveal the Windkessel vascular impedance properties of the patient.

[0030] The modified Windkessel model of the arterial system is used in the pulse contour analysis of the present invention. As shown in Fig. 1, the model includes components P_1, P_2, C_1, C_2, L and R in which:

C_1 = proximal compliance (mℓ/mm Hg)
C_2 = distal compliance (mℓ/mm Hg)
L = inertence (mm Hg/mℓ/s^2)
P_1 = proximal arterial pressure (mm Hg)
P_2 = brachial artery pressure (mm Hg)
R = peripheral resistance (dynes s cm^{-5})

[0031] As taught, for example, by Goldwyn and Watt in I.E.E.E. Trans. Biomed. Eng. 1967; 14:11-17, P_2 of the modified Windkessel model may be represented by the third order equation:

$$P_2(t)=A_1\exp(-A_2t)+A_3\exp(-A_4t)\cos(A_5t+A_6),$$

wherein:

$$C_1=\frac{mn-p}{mp}\,\frac{l}{R}$$

$$C_2=\frac{l}{m}\,\frac{l}{R}$$

$$L=\frac{m^2R}{mn-p}\text{ and}$$

wherein:

$$m = A_2 + 2A_4$$

$$n = 2A_2A_4 + A_4^2 + A_5^2$$

and

$$p = A_2(A_4^2 + A_5^2)$$

[0032] Thus, knowing R, which can be calculated from cardiac output and mean arterial pressure as follows:

$$R = \frac{\text{mean arterial pressure}}{\text{cardiac output (milliliters/minute)}}$$

C_1, C_2 and L are readily calculated.

[0033] To accomplish the above, software 50 includes routine 80-82, which comprises a modified Gauss-Newton parameter-estimating algorithm as for the example referenced by Watt and Burrus in their paper entitled, "Arterial Pressure Contour Analysis for Estimating Human Vascular Properties," Journal of Applied Physiology, 1976; 40:171-176. Routines 80-82 calculate the optimal values for coefficients A_1-A_6, using the measured arterial pressure data as $P_2(t)$. The algorithm uses an iterative approach which preferably provides fast convergence. The algorithm used in routines 80-82 include certain modifications. An automatic stopping procedure is included to stop iteration when an acceptable error level in the curve fitting threshold is reached or when convergence slows below a preset threshold. Also, when the process begins to diverge it returns to the previous best case. The routines also include a weighted iteration interval to improve convergence.

[0034] Once the coefficients A_1-A_6 are established for each pulse contour or waveform, the coefficients are used at routine 84 to calculate the C_1, C_2 and L vascular impedance parameters for each pulse contour or waveform. C_1, C_2 and L are all calculated in accordance with the formulas given above. Once calculated for each pulse contour the calculated values are averaged at routine 86, producing mean values more reliable for accuracy than any of the individual values. It shall be understood, however, that the averaging process is not essential. For instance, a median value could be selected for use if desired. At routine 88, the parameters may be stored in storage device 24 or RAM 22 for later retrieval. Finally, routine 90 causes the parameters C_1, C_2 and L to be displayed on display 18 and/or printed on printer 42.

[0035] Alternatively, routine 90 may additionally cause the display or report of cardiac output, mean arterial pressure, heart rate, and a tracing of the blood pressure waveforms.

[0036] Thus, the present invention provides an instrument which can noninvasively obtain measures of the modified Windkessel parameters. Accordingly, these parameters can be obtained quickly, inexpensively, easily and without discomfort to the patient, thereby encouraging more widespread beneficial use of the modified Windkessel model parameters in diagnosing, treating and monitoring patients with cardiovascular disease. Also, the vascular impedance measurement instrument provides a ready means to obtain modified Windkessel model parameters for subjects in clinical research trials and laboratory animals used in basic and applied biomedical research projects.

[0037] Although the invention has been described with respect to a second order modified Windkessel model of the vasculature, it is applicable to any model of the vasculature based on impedance which is derived from the blood pressure pulse contour of the arterial waveform and cardiac output. As an example, consider the first order model described by Spencer and Denison in "Pulsitile Blood Flow in the Vascular System. The Physiology of the Aorta and Major Arteries," in Hamilton W. F., Dow P. Editors Handbook of Physiology, Section 2; circulation, Vol. 2. Washington, D. C. 1963 American Physiological Society, page 799. Spencer and Denison's RC model treats the arterial system as a simple first-order model which discharges during diastole into a single resistance (the vascular bed). In this model, $T = C \times R$, where T = reciprocal of the exponential slope discharge, C = capacitance, and R = resistance. Therefore, $C = T/R$.

[0038] A number of studies have been conducted using such a first order arterial model, including a number of studies by the French researchers A. Ch. Simon and M. E. Safar. Some of these studies have established normal and abnormal values for the first order parameters C and R, which thus can be used to determine if a patient falls within a normal range or not. Thus, as used in the claims appended hereto, the term "vascular impedance model," shall be inclusive of both the modified Windkessel model, the first order RC arterial model, and any other impedance model of an essentially equivalent nature.

Claims

1. A vascular impedance properties measurement instrument, comprising:

   means (12, 30, 34) for measuring arterial pressure and producing a corresponding series of digitized data samples representing the waveform of the arterial blood pressure of a patient;
   means (14) for determining the mean arterial pressure of the patient from said data sample series;
   means (14) for determining a cardiac output value for the patient from said data sample series; and
   means (18; 42) for displaying or reporting one or more parameters;
   characterized by
   means (14) for determining the heart rate and the systolic ejection time of the patient from said data sample series; and
   means (14) for determining the stroke volume of the patient from said systolic ejection time, the patient's body surface area and the patient's age;
   wherein said means (14) for determining a cardiac output value for the patients determines the cardiac output value from said heart rate and said stroke volume;
   and further characterized by
   means (14) for determining for the patient one or more of the parameters of a vascular impedance model from said data sample series and from said cardiac output value.

2. The instrument of claim 1 wherein said means (14) for determining a cardiac output value for the patient determines the cardiac value from one or more further data values selected from the group of patient data comprising heart rate, age, height, weight and body surface area.

3. The instrument of claim 2 further wherein said means (14) for determining a cardiac output value includes means for determining stroke volume substantially in accordance with the following formula:

   $$SV = -6.6 + (0.25 \times ET) + (40.4 \times BSA) - (0.51 \times Age) - (0.62 \times HR),$$

   where SV equals stroke volume in mℓ/beat, ET is ejection time in msec, BSA is body surface area in square meters, Age is expressed in years, and HR is heart rate in beats per minute; and wherein cardiac output is calculated from stroke volume.

4. The instrument of anyone of the claims 1 to 3 further wherein the means (12, 30, 34) for measuring includes a transducer (34) for converting the arterial waveform to a corresponding electrical signal.

5. The instrument of claim 4 further comprising:

   a digital storage device (24);
   an analog-to-digital converter means (12) for digitizing the blood pressure waveform signal for a series of the patient's heart beats and storing the signal in the digital storage device (24);
   first processing means (14) connected to the digital storage device for processing the digitized blood pressure waveform signal to:

   (a) count the number of heart beats per unit time in the digitized blood pressure waveform to produce a heart rate signal for the patient, and
   (b) search a heart beat signal in the digitized blood pressure waveform, mark events indicating a beginning and ending of systole, and determine an ejection time signal by measuring a time between the marked events;

   second processing means (14) for receiving the heart rate signal, the ejection time signal, and values representing the patient's age and body surface area, and for generating therefrom an output signal indicative of the patient's cardiac output;
   third processing means (14) for receiving the digitized blood pressure waveform and for determining therefrom a mean arterial pressure signal indicative of the patient's mean arterial pressure;
   fourth processing means (14) for receiving the digitized blood pressure waveform and for marking segments of the waveform corresponding to a period of diastole in the heart; and
   fifth processing means (14) for receiving the marked segments of the digitized blood pressure waveform, the

cardiac output signal and the mean arterial pressure signal, for analyzing the shape of the marked diastolic segments and for determining one or more signals representing a condition of the patient's vasculature from the vascular impedance model, the one or more signals including at least a compliance signal representative of the flexibility or elasticity of the patient's blood vessels;
wherein the display means (18) is responsive to the one or more signals for displaying the magnitude thereof.

6. The instrument of anyone of the claims 1 to 5 further wherein said vascular impedance model is the modified Windkessel model of the vasculature.

7. The instrument of anyone of the claims 1 to 5 further wherein said vascular impedance model is a first order model of the vasculature.

8. The instrument of anyone of the claims 1 to 7 further wherein said means (12, 30, 34) for measuring includes a transducer unit for noninvasively measuring the blood pressure waveform.

9. The instrument of claim 8 wherein said transducer unit comprises:

arterial tonometry transducer means (34) for noninvasively measuring an arterial blood pressure of a patient using the technique of arterial tonometry and for generating a corresponding analog arterial blood pressure waveform; and
digitization means (12) for producing a corresponding series of digitized data samples representing the waveform of the arterial blood pressure of the patient.

10. The instrument of anyone of the claims 1 to 9 further comprising waveform marking means (14) for searching a heart beat signal in the digitized blood pressure waveform, for marking a segment of the heart beat signal, and for determining the ejection time signal by measuring the duration of said segment.

11. The instrument of claim 10 wherein the waveform marking means for marking a segment of the heartbeat signal is for marking a segment of the heartbeat signal corresponding to systole.

12. The instrument of claim 10 or 11 further comprising heart beat signal selection means (14) for selecting a group of representative heart beat signals from the digitized blood pressure waveform, said heart beat signals selected according to predetermined criteria whereby unwanted signals are filtered out.

13. The instrument of claim 10 further wherein the waveform marking means for marking a segment of the heartbeat signal is for marking a segment of the heartbeat signal corresponding to diastole.

14. The apparatus of claim 5, 10, 11, 12 or 13 further wherein the vascular impedance model is a modified Windkessel model of the vasculature.

15. The apparatus of claims 5, 10, 11, 12 or 13 further wherein the vascular impedance model is a first order model of the vasculature.

Patentansprüche

1. Instrument zur Messung von Gefäßimpedanzeigenschaften, mit:

Mitteln (12, 30, 34) zum Messen arteriellen Drucks und zum Erstellen einer entsprechenden Reihe digitalisierter Daten, die die Wellenform des arteriellen Blutdrucks eines Patienten darstellen;
einem Mittel (14) zum Bestimmen des mittleren arteriellen Drucks des Patienten anhand der Datenreihe;
einem Mittel (14) zum Bestimmen eines Herzauswurfleistungswertes für den Patienten anhand der Datenreihe; und
Mitteln (18; 42) zur Darstellung oder Wiedergabe eines oder mehrerer Parameter;
gekennzeichnet durch ein Mittel (14) zur Bestimmung der Herzfrequenz und der systolischen Auswurfdauer des Patienten anhand der Datenreihe; und
ein Mittel (14) zur Bestimmung des Schlagvolumens des Patienten anhand der systolischen Auswurfdauer, der Körperoberfläche des Patienten und dem Alter des Patienten;
wobei das Mittel (14) zur Bestimmung eines Herzauswurfleistungswertes für die Patienten den Herzauswurf-

leistungswert anhand der Herzfrequenz und des Schlagvolumens bestimmt;
und ferner gekennzeichnet durch ein Mittel (14) zur Bestimmung eines oder mehrerer der Parameter eines Gefäßimpedanzmodells für den Patienten anhand der Datenreihe.

2. Instrument nach Anspruch 1, wobei das Mittel (14) zum Bestimmen eines Herzauswurfleistungswertes für den Patienten den Herzwert anhand eines oder mehrerer weiterer Datenwerte bestimmt, die aus der Gruppe von Patientendaten ausgewählt sind, die Herzfrequenz, Alter, Größe, Gewicht und Körperoberfläche umfasst.

3. Instrument nach Anspruch 2, wobei das Mittel (14) zur Bestimmung des Herzauswurfleistungswertes Mittel aufweist zur Bestimmung des Schlagvolumens im wesentlichen gemäß nachfolgender Formel:

$$SV = -6.6 + (0.25 \times ET) + (40.4 \times BSA) - (0.51 \times Alter) - (0.62 \times HR),$$

wobei SV dem Schlagvolumen in ml/Schlag entspricht, ET die Auswurfdauer in msec ist, BSA die Körperoberfläche in qm ist, das Alter in Jahren ausgedrückt wird und HR die Herzfrequenz in Schlägen pro Minute ist; und wobei die Herzauswurfleistung anhand des Schlagvolumens errechnet wird.

4. Instrument nach einem der Ansprüche 1 bis 3, wobei die Mittel (12, 30, 34) zum Messen einen Wandler (34) zum Wandeln der arteriellen Wellenform in ein entsprechendes elektrisches Signal aufweisen.

5. Instrument nach Anspruch 4, mit:

einer digitalen Speichereinrichtung (24);
einem Analog/Digital-Wandler (12) zum Digitalisieren des Blutdruckwellenformsignals für eine Reihe von Herzschlägen des Patienten und zum Abspeichern des Signals in der digitalen Speichereinrichtung (24);
ersten Verarbeitungsmitteln (14), die an die digitale Speichereinrichtung angeschlossen sind, zum Verarbeiten des digitalisierten Blutdruckwellenformsignals, um:

(a) die Anzahl der Herzschläge pro Zeiteinheit in der digitalisierten Blutdruckwellenform zu zählen, um ein Herzfrequenzsignal für den Patienten zu erzeugen, und
(b) ein Herzschlagsignal in der digitalisierten Blutdruckwellenform zu suchen, Vorkommnisse zu markieren, die einen Beginn und ein Ende einer Systole indizieren, und ein Auswurfdauersignal zu bestimmen, indem eine Dauer zwischen den markierten Vorkommnissen gemessen wird;

zweiten Verarbeitungsmitteln (14) zum Empfangen des Herzfrequenzsignals, des Auswurfdauersignals und von Werten, die das Alter des Patienten und die Körperoberfläche darstellen, und um daraus ein Auswurfsignal zu erzeugen, das die Herzauswurfleistung des Patienten anzeigt;
dritten Verarbeitungsmitteln (14) zum Empfangen der digitalisierten Blutdruckwellenform und um daraus ein Arteriendruck-Mittelwertsignal zu bestimmen, das den mittleren arteriellen Druck des Patienten anzeigt;
vierten Verarbeitungsmitteln (14) zum Empfangen der digitalisierten Blutdruckwellenform und zum Markieren von Anteilen der Wellenform, die einer Diastolenperiode in dem Herzen entsprechen; und
fünften Verarbeitungsmitteln (14) zum Empfangen der markierten Anteile der digitalisierten Blutdruckwellenform, des Herzauswurfsignals und des Arteriendruck-Mittelwertsignals, um die Gestalt der markierten diastolischen Anteile zu analysieren und um ein oder mehrere Signale anhand des Gefäßimpedanzmodells zu bestimmen, die einen Zustand des Gefäßsystems des Patienten darstellen, wobei das oder die Signal(e) wenigstens ein Übereinstimmungssignal aufweisen, das die Flexibilität oder Elastizität der Blutgefäße des Patienten darstellt; wobei das Anzeigemittel (18) auf das oder die Signal(e) anspricht, um deren Größe darzustellen.

6. Instrument nach einem der Ansprüche 1 bis 5, wobei das Gefäßimpedanzmodell das modifizierte Windkessel-Modell des Gefäßsystems ist.

7. Instrument nach einem der Ansprüche 1 bis 5, wobei das Gefäßimpedanzmodell ein Modell erster Ordnung des Gefäßsystems ist.

8. Instrument nach einem der Ansprüche 1 bis 7, wobei die Mittel (12, 30, 34) zum Messen eine Wandlereinheit für nicht-invasives Messen der Blutdruckwellenform aufweisen.

9. Instrument nach Anspruch 8, wobei die Wandlereinheit aufweist:

arterielle Tonometrie-Wandler (34) zum nicht-invasiven Messen eines arteriellen Blutdrucks eines Patienten unter Anwendung der Technik der arteriellen Tonometrie und zum Erzeugen einer entsprechenden analogen Wellenform des arteriellen Blutdrucks; und
Digitalisierungsmittel (12) zum Erzeugen einer entsprechenden Reihe von digitalisierten Daten, die die Wellenform des arteriellen Blutdrucks des Patienten darstellen.

10. Instrument nach einem der Ansprüche 1 bis 9, mit einem Wellenform-Markierungsmittel (14) zum Suchen eines Herzschlagsignals in der digitalisierten Blutdruckwellenform, um einen Anteil des Herzschlagsignals zu markieren und um das Auswurfdauersignal durch Messung der Dauer des Anteils zu bestimmen.

11. Instrument nach Anspruch 10, wobei das Wellenform-Markierungsmittel zum Markieren eines Anteils des Herzschlagsignals zum Markieren eines Anteils des Herzschlagsignals vorgesehen ist, der einer Systole entspricht.

12. Instrument nach Anspruch 10 oder 11, mit einem Herzschlagsignal-Auswahlmittel (14) zum Auswählen einer Gruppe repräsentativer Herzschlagsignale aus der digitalisierten Blutdruckwellenform, wobei die Auswahl der Herzschlagsignale nach vorgegebenen Kriterien erfolgt, wodurch unerwünschte Signale ausgefiltert werden.

13. Instrument nach Anspruch 10, wobei das Wellenform-Markierungsmittel zum Markieren eines Anteils des Herzschlagsignals zum Markieren eines Anteils des Herzschlagsignals vorgesehen ist, der einer Diastole entspricht.

14. Vorrichtung nach Anspruch 5, 10, 11, 12 oder 13, wobei das Gefäßimpedanzmodell ein modifiziertes Windkessel-Modell des Gefäßsystems ist.

15. Vorrichtung nach Anspruch 5, 10, 11, 12 oder 13, wobei das Gefäßimpedanzmodell ein Modell erster Ordnung des Gefäßsystems ist.

Revendications

1. Instrument de mesure de propriétés d'impédance vasculaire, comprenant :

des moyens (12, 30, 34) pour mesurer la tension artérielle et produire une série correspondante d'échantillons de données numérisés représentant la forme d'onde de la pression sanguine artérielle d'un patient ;
des moyens (14) pour déterminer la tension artérielle moyenne du patient à partir de ladite série d'échantillons de données ;
des moyens (14) pour déterminer une valeur de débit cardiaque pour le patient à partir de ladite série d'échantillons de données : et
des moyens (18; 42) pour afficher ou signaler un ou plusieurs paramètres ;
caractérisé par
des moyens (14) pour déterminer la fréquence cardiaque et le temps d'éjection systolique du patient à partir de ladite série d'échantillons de données ; et
des moyens (14) pour déterminer le volume de course du patient à partir dudit temps d'éjection systolique, de l'aire de surface du corps du patient et de l'âge du patient ;
dans lequel lesdits moyens (14) pour déterminer une valeur de débit cardiaque pour les patients déterminent la valeur de débit cardiaque à partir de ladite fréquence cardiaque et dudit volume de course ;
et caractérisé en outre par
des moyens (14) pour déterminer pour le patient un ou plusieurs des paramètres d'un modèle d'impédance vasculaire à partir de ladite série d'échantillons de données et à partir de ladite valeur de débit cardiaque.

2. Instrument selon la revendication 1, dans lequel lesdits moyens (14) pour déterminer une valeur de débit cardiaque pour le patient déterminent la valeur cardiaque à partir d'une ou de plusieurs valeurs de données sélectionnées dans le groupe de données du patient comprenant la fréquence cardiaque, l'âge, la taille, le poids et l'aire de surface du corps.

3. Instrument selon la revendication 2, dans lequel en outre, lesdits moyens (14) pour déterminer une valeur de débit cardiaque incluent des moyens pour déterminer un volume de course substantiellement conformément à la formule suivante :

$$SV = -6,6 + (0,25 \times ET) + (40,4 \times BSA) - (0,51 \times Age) - (0,62 \times HR),$$

où SV est le volume de course en ml/pulsation, ET est le temps d'éjection en ms, BSA est l'aire de surface du corps en mètres carrés, Age est exprimé en années, et HR est la fréquence cardiaque en pulsations par minute; et dans lequel le débit cardiaque est calculé d'après le volume de course.

4. Instrument selon l'une quelconque des revendications 1 à 3, dans lequel en outre, les moyens (12, 30, 34) de mesure incluent un transducteur (34) pour convertir la forme d'onde artérielle en un signal électrique correspondant.

5. Instrument selon la revendication 4, comprenant en outre :

un dispositif de stockage numérique (24) ;
des moyens de conversion analogique/ numérique (12) pour numériser le signal de forme d'onde de la pression sanguine pour une série des pulsations de coeur du patient et pour stocker le signal dans le dispositif de stockage numérique (24) ;
des premiers moyens de traitement (14) connectés au dispositif de stockage numérique pour traiter le signal numérisé de forme d'onde de la pression sanguine pour :

(a) compter le nombre de pulsations de coeur par temps unitaire dans la forme d'onde de pression sanguine numérisée pour produire un signal de fréquence cardiaque pour le patient, et
(b) chercher un signal de pulsation cardiaque dans la forme d'onde de pression sanguine numérisée, marquer des événements indiquant un début et une fin de systole, et déterminer un signal de temps d'éjection en mesurant une durée entre les événements marqués ;

des deuxièmes moyens de traitement (14) pour recevoir le signal de fréquence cardiaque, le signal de temps d'éjection, et des valeurs représentant l'âge et l'aire de surface du corps du patient et pour générer à partir de celles-ci un signal de débit indicatif du débit cardiaque du patient ;
des troisièmes moyens de traitement (14) pour recevoir la forme d'onde de pression sanguine numérisée et pour déterminer à partir de celle-ci un signal de tension artérielle moyenne indicatif de la tension artérielle moyenne du patient ;
des quatrièmes moyens de traitement (14) pour recevoir la forme d'onde de pression sanguine numérisée et pour marquer des segments de la forme d'onde correspondant à une période de diastole dans le coeur ; et
des cinquièmes moyens de traitement (14) pour recevoir les segments marqués de la forme d'onde de pression sanguine numérisée, le signal de débit cardiaque et le signal de tension artérielle moyenne, pour analyser la forme des segments diastoliques marqués et pour déterminer un ou plusieurs signaux représentant une condition de la vasculature du patient d'après le modèle d'impédance vasculaire, ledit un ou plusieurs signaux incluant au moins un signal de conformité représentatif de la souplesse ou de l'élasticité des vaisseaux sanguins du patient ;
dans lequel les moyens d'affichage (18) répondent audit un ou plusieurs signaux pour afficher son ampleur.

6. Instrument selon l'une quelconque des revendications 1 à 5, dans lequel en outre, ledit modèle d'impédance vasculaire est le modèle de Windkessel modifié de la vasculature.

7. Instrument selon l'une quelconque des revendications 1 à 5, dans lequel en outre, ledit modèle d'impédance vasculaire est un modèle de premier ordre de la vasculature.

8. Instrument selon l'une quelconque des revendications 1 à 7, dans lequel en outre, lesdits moyens (12, 30, 34) de mesure incluent une unité de transducteur pour mesurer de façon non invasive la forme d'onde de pression sanguine.

9. Instrument selon la revendication 8, dans lequel ladite unité de transducteur comprend :

des moyens de transducteur de tonométrie artérielle (34) pour mesurer de façon non invasive une pression sanguine artérielle d'un patient en utilisant la technique de la tonométrie artérielle et pour générer une forme d'onde de pression sanguine artérielle analogique correspondante ; et
des moyens de numérisation (12) pour produire une série correspondante d'échantillons de données numérisés représentant la forme d'onde de la pression sanguine artérielle du patient.

10. Instrument selon l'une quelconque des revendications 1 à 9, comprenant en outre des moyens de marquage de forme d'onde (14) pour chercher un signal de pulsation cardiaque dans la forme d'onde de pression sanguine artérielle numérisée, pour marquer un segment du signal de pulsation cardiaque, et pour déterminer le signal de temps d'éjection en mesurant la durée dudit segment.

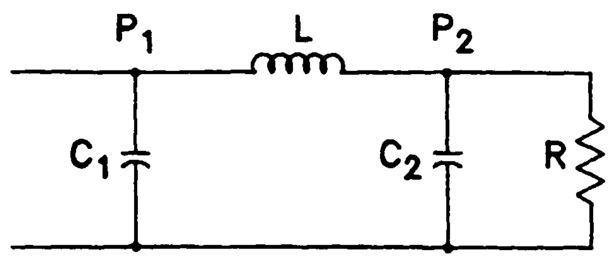
11. Instrument selon la revendication 10, dans lequel les moyens de marquage de forme d'onde pour marquer un segment du signal de pulsation cardiaque sont destinés à marquer un segment du signal de pulsation cardiaque correspondant à la systole.

12. Instrument selon la revendication 10 ou 11, comprenant en outre des moyens de sélection de signal de pulsation cardiaque (14) pour sélectionner un groupe de signaux de pulsation cardiaque représentatifs à partir de la forme d'onde de pression sanguine numérisée, lesdits signaux de pulsation cardiaque sélectionnés selon des critères prédéterminés, de sorte que des signaux indésirables sont éliminés par filtrage.

13. Instrument selon la revendication 10, dans lequel en outre, les moyens de marquage de forme d'onde pour marquer un segment du signal de pulsation cardiaque sont destinés à marquer un segment du signal de pulsation cardiaque correspondant à la diastole.

14. Dispositif selon la revendication 5, 10, 11, 12 ou 13, dans lequel en outre, le modèle d'impédance vasculaire est un modèle de Windkessel modifié de la vasculature.

15. Dispositif selon la revendication 5, 10, 11, 12 ou 13, dans lequel en outre, le modèle d'impédance vasculaire est un modèle de premier ordre de la vasculature.



C_1 = PROXIMAL ARTERIAL COMPLIANCE (m1/mm Hg);

C_2 = DISTAL ARTERIAL COMPLIANCE (m1/mm Hg);

L = INERTENCE (mm Hg/m1/s(2));

P_1 = PROXIMAL ARTERIAL (AORTIC) PRESSURE (mm Hg);

P_2 = DISTAL ARTERIAL (BRACHIAL) PRESSURE (mm Hg); AND

R = PERIPHERAL RESISTANCE (DYNES s cm^{-5}).

FIG. 1

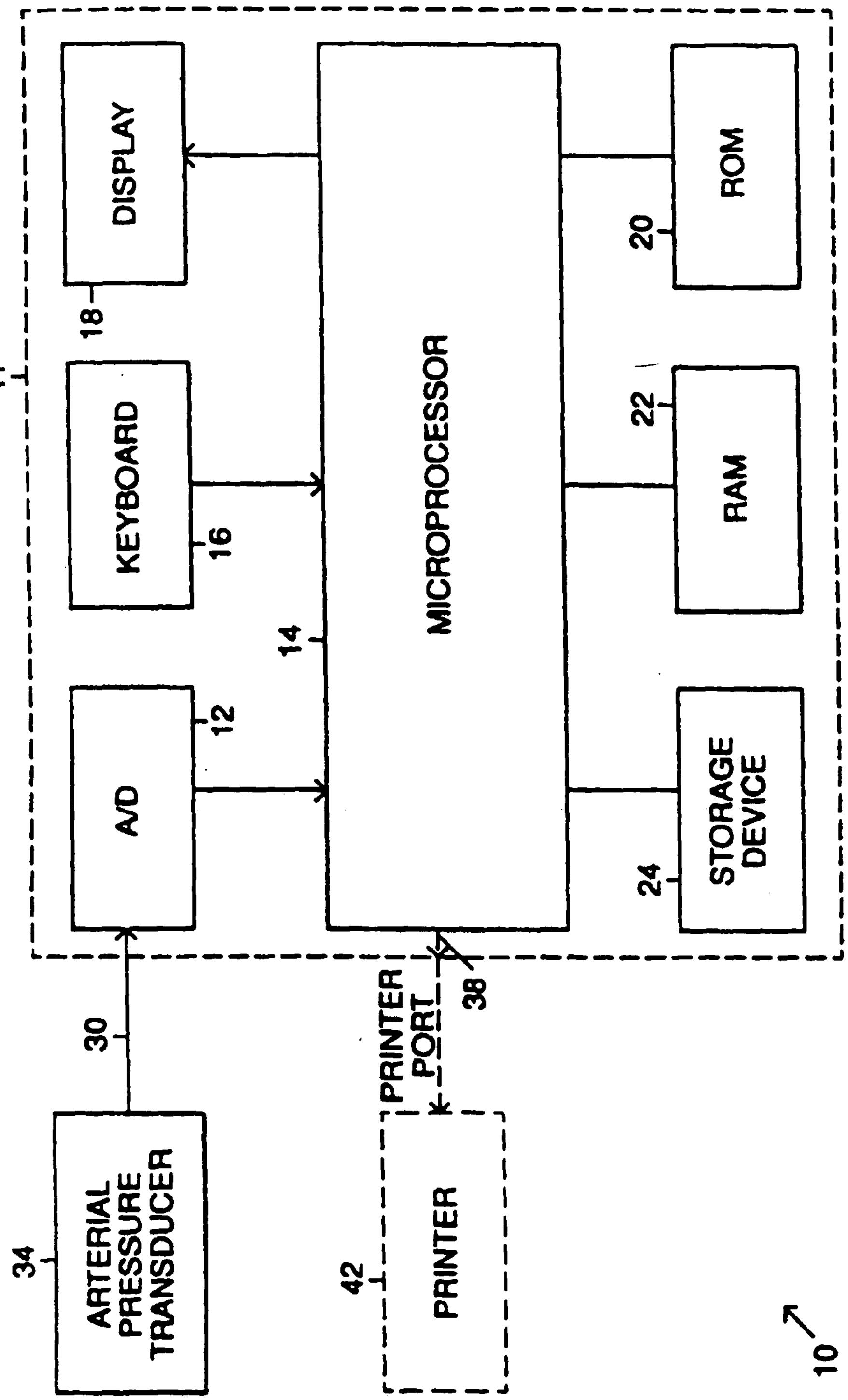

DISPLAY
KEYBOARD
A/D
MICROPROCESSOR
ROM
RAM
STORAGE DEVICE
ARTERIAL PRESSURE TRANSDUCER
PRINTER PORT
PRINTER
11
12
14
16
18
20
22
24
30
34
38
42
10

FIG. 2

FIG. 3

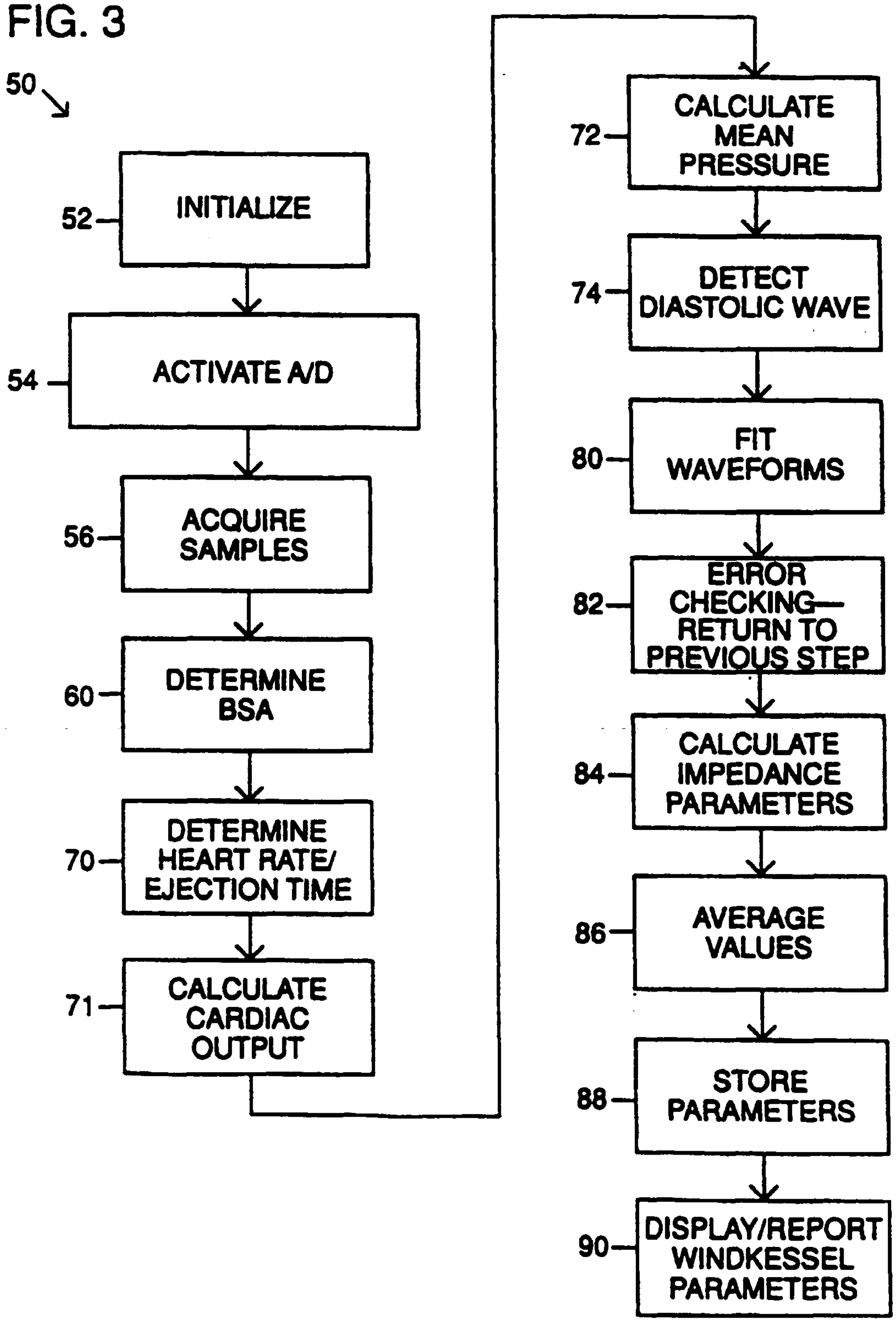

50
52
INITIALIZE
54
ACTIVATE A/D
56
ACQUIRE SAMPLES
60
DETERMINE BSA
70
DETERMINE HEART RATE/ EJECTION TIME
71
CALCULATE CARDIAC OUTPUT
72
CALCULATE MEAN PRESSURE
74
DETECT DIASTOLIC WAVE
80
FIT WAVEFORMS
82
ERROR CHECKING— RETURN TO PREVIOUS STEP
84
CALCULATE IMPEDANCE PARAMETERS
86
AVERAGE VALUES
88
STORE PARAMETERS
90
DISPLAY/REPORT WINDKESSEL PARAMETERS

FIG. 4

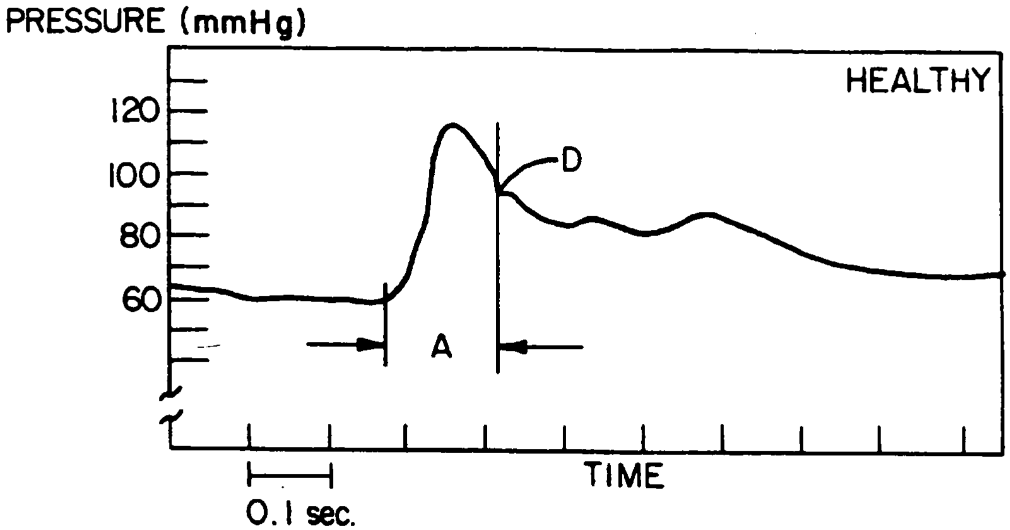
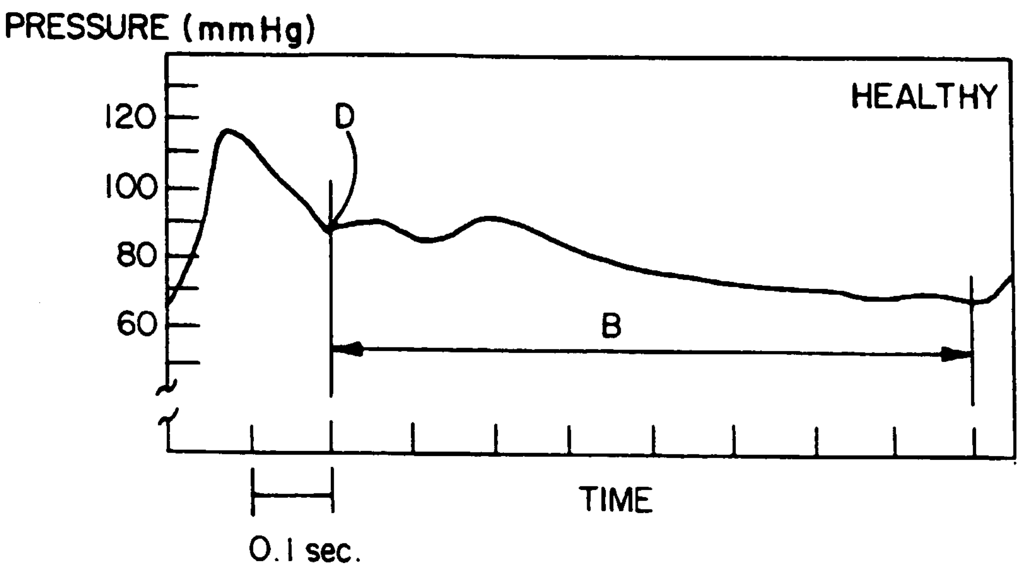

PRESSURE (mmHg)
HEALTHY
120
100
80
60
D
A
TIME
0.1 sec.

FIG. 5


PRESSURE (mmHg)
HEALTHY
120
100
80
60
D
B
TIME
0.1 sec.